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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/531,969	03/21/2000	Jan Geliebter	96700/596	6902

7590

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EXAMINER

PARAS JR, PETER

ART UNIT

PAPER NUMBER

1632

DATE MAILED: 11/14/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Advisory Action**

Application No.

09/531,969

Applicant(s)

GELIEBTER ET AL.

Examiner

Peter Paras, Jr.

Art Unit

1632

**--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

THE REPLY FILED 29 October 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

**PERIOD FOR REPLY [check either a) or b)]**

- a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.
- b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on \_\_\_\_\_. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.
2. ☐ The proposed amendment(s) will not be entered because:
- (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);
- (b) ☐ they raise the issue of new matter (see Note below);
- (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or
- (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

NOTE: \_\_\_\_\_.

3. ☒ Applicant's reply has overcome the following rejection(s): See Continuation Sheet.
4. ☐ Newly proposed or amended claim(s) \_\_\_\_\_ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).
5. ☒ The a) ☐ affidavit, b) ☐ exhibit, or c) ☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: See Continuation Sheet.
6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.
7. ☒ For purposes of Appeal, the proposed amendment(s) a) ☐ will not be entered or b) ☒ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

The status of the claim(s) is (or will be) as follows:

Claim(s) allowed: \_\_\_\_\_.

Claim(s) objected to: \_\_\_\_\_.

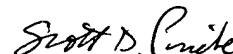
Claim(s) rejected: 1,9 and 37-49.

Claim(s) withdrawn from consideration: \_\_\_\_\_.

8. ☐ The proposed drawing correction filed on \_\_\_\_\_ is a) ☐ approved or b) ☐ disapproved by the Examiner.
9. ☐ Note the attached Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_.
10. ☐ Other: \_\_\_\_\_

Continuation of 3. Applicant's reply has overcome the following rejection(s): the previous new matter rejection set forth in the Final Office action on pages 8-10.

Continuation of 5. does NOT place the application in condition for allowance because: Applicant's arguments have not overcome the rejections of record. All of the rejections are maintained for the reasons of record set forth in the Final office action of 7/29/02. With regard to the written description rejection, Applicants have argued that potassium channels other Maxi-K or KATP are involved in enhancing relaxation of genitourinary smooth muscle. Applicants have provided the Dorschner, Lee and Benevides references in support of their arguments. See pages 4-5 of the amendment. In response, the Examiner maintains that the evidence of record has not described other nucleic acid sequence encoding potassium channels that when introduced in genitourinary smooth muscle cells can cause less heightened contractility. The Dorschner, Lee and Benevides references while hinting that more potassium channels may be involved modulating genitourinary smooth muscle contractility do not recite which potassium channels other than Maxi-K or KATP may perform this function. In particular, the references do not discuss which other potassium channels, when introduced in the context of a nucleic acid sequence, into genitourinary smooth muscle can cause less heightened contractility. It is maintained that Applicant is not in possession of the nucleic acid sequences encoding the other potassium channels. With regard to the enablement rejection, Applicants have argued because the evidence of record has shown that two separate potassium channel genes are demonstrated to provide sufficient expression in smooth muscle cells of two separate urogenital smooth muscles, the skilled artisan would understand that there is a reasonable likelihood of success in using another potassium channel gene to enhance relaxation of genitourinary smooth muscle. Applicants go on to argue that examples are not necessary to satisfy 112, first paragraph. In response, the Examiner maintains that the claims are enabled to the extent of the Maxi-K and KATP. As Applicants have correctly pointed out the evidence of record has provided working examples that exemplify the use of nucleic acid sequences encoding Maxi-K and KATP for causing less heightened contractility of corporal and bladder smooth muscle. However, the evidence of record has not provided guidance or working examples for use of nucleic acid sequences encoding other potassium channels to cause less heightened contractility of urogenital smooth muscle. While working examples are not required to enable the claims, lack of working examples may be not sufficient to overcome the unpredictability of the art with respect to gene therapy. The evidence of record suggests that not all K<sup>+</sup> channel subtypes are expressed in smooth muscle, particularly urogenital smooth muscle. Moreover, Applicant's specification suggests that only KATP and Maxi-K are physiologically relevant given the evidence provided from human corporal smooth muscle. See the Final Office action on pages 6-7. Accordingly, the rejection is maintained.



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PRIMARY EXAMINER